657—20.3 (124,126,155A) General requirements.

20.3(1) *Compounding commercially available product.* Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace, if the compounded product is changed to produce for that patient a significant difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if use of the compounded product is in the best interest of the patient. "Significant difference" would include the removal of a dye for a medical reason such as an allergic reaction. When a compounded product is to be dispensed in place of a commercially available product, the prescriber and patient shall be informed that the product will be compounded.

20.3(2) *Substances and components.* Pharmacists shall receive, store, and use bulk drug substances manufactured by an establishment that is registered with the FDA under the Federal Food, Drug, and Cosmetic Act and that, if requested, will provide a valid certificate of analysis for each drug product. Certificates of analysis shall be maintained pursuant to rule 657—20.12(124,126,155A). Bulk drug substances to be used in compounding drugs:

a. When a monograph exists, shall comply with the applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph and the USP chapter on pharmacy compounding; or

b. If not subject to a monograph, shall be ingredients of drugs that the FDA has approved; or

c. If not subject to a monograph and not ingredients of FDA-approved drugs, shall appear on the FDA list of approved bulk drug substances not subject to a monograph; or

d. If not subject to a monograph, peer-reviewed medical literature shall support the use and, in the professional judgment of the pharmacist, demonstrate the safety and effectiveness of the substance.

20.3(3) *Prescriber/patient/pharmacist relationship.* A prescription for a compounded drug shall be authorized by the prescriber for a specific patient. Prescriptions for all products compounded at the pharmacy shall be maintained on file at the pharmacy as required by Iowa law. Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions generated solely within an established pharmacist/patient/prescriber relationship. Compounding based on a prescription history is bulk compounding and shall comply with the requirements of rule 657—20.11(126).

20.3(4) *Advertising and resale of compounded drug products.* The sale of compounded drug products to other pharmacies or to prescribers, except as provided in this subrule, is considered manufacturing.

a. Sale to practitioner for office use. A pharmacist shall not offer compounded drug products to other licensed persons or commercial entities for subsequent resale except in the course of professional practice for a practitioner to administer to an individual patient.

b. Sale to hospital pharmacy for administration to a specific patient. A pharmacy may sell to a hospital pharmacy a compounded drug product prepared pursuant to a prescriber's authorization for administration to a specific patient. The label affixed to the compounded drug product shall identify the pharmacy that compounded the product as the dispensing pharmacy. The original prescription drug order shall be maintained by the dispensing pharmacy. These rules shall not prohibit the hospital pharmacy from billing the patient or the patient's fiscal agent for a compounded product prepared for the patient and purchased by the hospital pharmacy pursuant to this subrule.

c. Advertising compounding services. A compounding pharmacy or pharmacist may advertise or otherwise promote the fact that the pharmacy or pharmacist provides prescription drug compounding services. A compounding pharmacy or pharmacist shall not make a claim, assertion, or inference of professional superiority in the compounding of drug products that cannot be substantiated. All advertisements shall meet the requirements contained in rule 657—8.12(126,147).

d. Central fill or processing of compounded drug products. Nothing in these rules shall prohibit the centralized filling or processing of a prescription drug order for a compounded drug product by a central fill or processing pharmacy on behalf of an originating pharmacy as provided in 657—Chapter 18.

e. *Compounding for research.* A compounding pharmacy may compound drug products and placebos for dispensing to subjects involved in an approved blinded university or college research project. Drug products and placebos compounded for this purpose shall be labeled as provided in the research protocol and may be dispensed directly to patients, delivered to another pharmacy for delivery to patients, or delivered to the researcher for delivery to patients. Provisions of subrule 20.3(1) prohibiting the compounding of commercially available products shall not apply to the compounding of products and placebos for research pursuant to this paragraph.

20.3(5) *Compounding prohibited.* Pharmacists shall not compound:

a. A drug that has been identified by the FDA as withdrawn or removed from the market because the drug was found to be unsafe or ineffective.

b. Regularly or in inordinate amounts drugs that are essentially copies of a commercially available drug product except as provided in subrule 20.3(1).

c. Drugs that have been identified by the FDA or the board as products which may not be compounded.

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